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July 15, 2002

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Re: URGENT -- Protest of Certificate of Correction
U.S. Patent No. 6,030,790

Ladies and Gentlemen:

We are counsel for Scantibodies Clinical Laboratory, Inc. and Scantibodies Laboratory, Inc. ("Scantibodies"). Scantibodies is the defendant in a patent infringement action initiated by Nichols Institute Diagnostics, Inc. ("Nichols") in the United States District Court for the Southern District of California (Case No. 02 CV 0046 B), asserting infringement of U.S. Patent No. 6,030,790 ("'790 patent"). We write to advise you of that lawsuit and to protest the petition for certificate of correction filed by Nichols, seeking correction of the inventorship of the '790 patent ("Nichols' Petition"). No action should be taken on Nichols' Petition and, in particular, no certificate of correction should be granted or published, until further direction from the District Court before whom this very inventorship issue is pending in a summary judgment motion scheduled for hearing on August 5, 2002. The Court has assumed

jurisdiction of inventorship of the '790 patent pursuant to 35 U.S.C. § 256 and that jurisdiction should be respected by the PTO.

On May 16, 2002, Scantibodies filed a motion for summary judgment of invalidity due to nonjoinder of inventor under 35 U.S.C. Section 102(f) based on the undisputed evidence that the patent failed to list Wolf-Georg Forssmann as a co-inventor. Due to a conflict in the Court's calendar, the hearing on this motion was rescheduled for August 5, 2002. A copy of the motion and the Court's scheduling Order setting the August 5 hearing date is enclosed.

We understand that during the delay caused by this rescheduling Nichols filed a petition for correction of inventorship seeking to add Forssmann as a co-inventor. We also understand that the PTO has granted but not yet published a certificate of correction. We were informed by Ms. Cecelia Newman that publication of the certificate of correction may take place as early as the morning of July 16, 2002. Therefore, your urgent attention to this matter is required.

Nichols' Petition was filed without any notice to the Court or to Scantibodies. Nichols' improperly seeks to have the PTO correct the inventorship error *ex parte* and deprive the District Court of its jurisdiction over correction of inventorship under 35 U.S.C. § 256, which was established by the filing of the Nichols lawsuit and the Scantibodies motion pointing out the incorrect inventorship.

The PTO should not allow its process to be abused for the purpose of seeking to deprive the District Court of control of a matter over which it has already assumed jurisdiction. Under 35 U.S.C. § 256, when incorrect inventorship has been raised in ongoing litigation, the patentee must immediately move the District Court to correct the inventorship in an evidentiary hearing under section 256. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1350-51 ((Fed Cir. 1998) ("the patentee must claim entitlement to relief under the statute and the court must give the patentee an opportunity to correct inventorship."). Nichols seeks to circumvent the required evidentiary hearing on the factual prerequisites for correction of inventorship, including for example the issue of deceptive intent, by having the PTO issue a certificate of correction based only on an *ex parte* petition. This is a violation of the District Court's jurisdiction over this issue and of Scantibodies legal rights.

The District Court will hear Scantibodies' summary judgment motion on August 5, 2002, and will then be able to provide guidance to the parties on how this matter should be resolved. Scantibodies respectfully submits that the PTO should take no action on Nichols' petition, and must not issue or publish a certificate of correction, until Nichols provides the PTO with an Order from the District Court allowing the certificate of correction as contemplated by section 256 and 37 C.F.R. § 1.324(a).

We stand ready to provide the PTO with any information it needs to ensure that this matter is handled properly without prejudice to the United Stated District Court lawsuit filed by Nichols and the legal rights of Scantibodies in that lawsuit.

Sincerely,

Kate H. Murashige

Kate H. Murashige
Reg No. 29,959

Sincerely,

Peng Chen
Reg. No. 43,543

Enclosures

U.S. District Court
Southern District of California
880 Front Street, Room 4290
San Diego, CA 92101-8900

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To: David Doyle

From: Clerk U.S. District Court

Date 06/20/02

Fax queued: 06/20/02 at 08:55:40

CASE: 0246-CV #00050

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

NICHOLS INSTITUTE DIAGNOSTICS, INC., a California Corporation,

Plaintiff,

vs.

SCANTIBODIES CLINICAL LABORATORY, INC., a California Corporation; SCANTIBODIES LABORATORY, INC., a California Corporation; and DOES 1 through 10,

Defendants.

CIV. NO. 02CV0046-B (LAB)

ORDER

Due to a conflict in the Court's calendar, the hearing of Defendants' Motion for Summary Judgment and of Plaintiff's Motion for More Definite Statement or to Strike, both of which are currently scheduled to be heard on July 29, 2002, are hereby rescheduled for August 5, 2002. The hearing of both motions will take place August 5, 2002, at 10:30 a.m. in Courtroom Two.

IT IS SO ORDERED.

DATED: 6-19-02

Rudi M. Brewster

UNITED STATES SENIOR DISTRICT JUDGE

cc: All Parties
Magistrate Judge

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02CV0046

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

NICHOLS INSTITUTE DIAGNOSTICS, INC., a California corporation,

Plaintiff,

v.

SCANTIBODIES CLINICAL LABORATORY, INC., a California corporation; and SCANTIBODIES LABORATORY, INC., a California corporation,

Defendants.

SCANTIBODIES CLINICAL LABORATORY, INC., a California corporation; and SCANTIBODIES LABORATORY, INC., a California corporation,

Counter-Claimants

v.

NICHOLS INSTITUTE DIAGNOSTICS, INC., a California corporation,

Counter-Defendants.

No. 02 CV 0046 B (LAB)

SCANTIBODIES CLINICAL LABORATORY, INC. AND SCANTIBODIES LABORATORY, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT PURSUANT TO 35 U.S.C. § 102(f) FOR NONJOINDER OF CO-INVENTOR

Date: July 15, 2002
Time: 10:30 a.m.
Courtroom 2

Hon. Rudi M. Brewster

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I. INTRODUCTION

Nichols Institute Diagnostics, Inc. ("Nichols") commenced this action for alleged infringement of U.S. Patent No. 6,030,790 (the "'790 patent"). But this case should go no further. Nichols' patent suffers from a fundamental flaw and is invalid on its face. The applicants for the '790 patent failed to identify and join all the inventors in their application to the United States Patent and Trademark Office ("PTO"). They failed to satisfy one of the fundamental conditions for obtaining a valid patent -- naming all the correct inventors. In other words, the applicants never properly "got off the starting blocks" in their efforts to obtain a valid patent from the PTO.

The issue presented in this motion is very straightforward. The Court need look only to the patent documents themselves to decide this discrete invalidity issue.

The '790 patent lists only three co-inventors on its face: Knut Adermann ("Adermann"), Dieter Hock ("Hock"), and Markus Mägerlein ("Mägerlein"). The '790 is the "national stage" of an earlier international patent application filed under the Patent Cooperation Treaty ("PCT"). The PCT provides a standard set of policies and procedures for filing a single application in multiple jurisdictions based on the same invention. 4 Donald Chisum, *Chisum on Patents,* § 14.02 [4] at n.1 (Cumm. Supp. Oct. 2001). In order for the '790 to claim the filing date of the PCT Application, it must have been the same application and the same subject matter. Indeed, as was appropriate under the PCT and the patent laws of the United States, the '790 claimed the filing date of the earlier PCT Application.

Although the '790 patent originated in the PTO as the PCT Application -- and was for the same invention -- the '790 patent does not name the same inventors. The PCT Application identified Adermann, Hock, Mägerlein ***and Wolf-Georg Forssmann*** as inventors. The '790, however, **does not include Forssmann.**

The omission of Forssmann from the U.S. application for the '790 patent renders it invalid under 35 U.S.C. § 102(f) as a matter of law. Having commenced an action based on an invalid patent, Nichols now has only two options: either promptly seek judicial correction

of the inventorship error under the procedure set forth in 35 U.S.C. § 256 or have the '790 patent declared invalid for nonjoinder of inventors. In either case, this costly lawsuit is premature and should proceed no further.

II. STATEMENT OF THE FACTS

On September 28, 1994, an application was filed with the German Patent Office, Federal Republic of Germany. *See* Ex. A attached to Declaration of M. Andrew Woodmansee in Support of Scantibodies Clinical Laboratory, Inc. and Scantibodies Laboratory, Inc.'s Motion for Summary Judgment Pursuant to 35 U.S.C. § 102(f) ("Woodmansee Decl."). That patent, DE 44 34 551 A1, identified four inventors on its face: Adermann, Hock, Mägerlein ***and Forssmann***. *Id.* According to the abstract:

> The invention relates to peptides from the human parathyroid (hPTH) sequence (1-37), containing α-helical amino acid sequence regions, where said peptides are capable of inducing antibodies when injected into animals. The invention also relates to a diagnostic agent and antibodies obtainable by vaccination of animals with the peptides in question.

(Woodmansee Decl., Ex. A at p. 3)

The German patent (DE 44 34 555 A1) formed the basis for an application filed on September 22, 1995 with the World Intellectual Property Organization and published pursuant to the PCT. The PCT Application (WO 96/10041) claimed priority on its face to the 1994 German application. (Woodmansee Decl., Ex. B at p. 12) Like its German counterpart, the PCT named the same four inventors: Adermann, Hock, Mägerlein ***and Forssmann***. (*Id.*) The abstract of the PCT Application described the same subject matter as the German application:

> The invention concerns peptides from the human parathyroid (hPTH) sequence (1-37) and containing α-helical amino acid sequence regions and/or non-structured amino acid sequence regions. The said peptides are capable of inducing antibodies when injected into animals. The invention also concerns a diagnostic agent and antibodies obtainable by vaccination of animals with the peptides in question.

(Woodmansee Decl., Ex. B at p. 12)

Based on the disclosure and filing date of the PCT Application (September 22, 1995), an application was filed with the United States Patent and Trademark Office. That application ultimately issued as the '790 patent. The abstract of the '790 patent describes its subject matter and claimed inventions as follows:

> The present invention is directed to peptides from the sequence of hPTH (1-37), which contain α-helical amino acid sequence regions and/or non-structured amino acid sequence regions, said peptides being capable of inducing antibodies when injected into animals. Furthermore, the invention is directed to a diagnostic agent and antibodies obtainable by immunizing animals using the peptides according to the invention.

(Woodmansee Decl., Ex. C at p. 30)

The application for the '790 patent was submitted to the PTO as the national stage of the PCT Application. The application claimed the benefit and filing date of the PCT Application. (*Id.*) Indeed, the named inventors on the application -- Adermann, Hock and Mägerlein -- submitted a declaration to the PTO claiming inventorship of the invention sought in the application and confirming that the specification of the invention had first been filed in the PCT Application. The inventors' declaration states, under penalty of perjury, in pertinent part:

> As a below named inventor, I hereby declare that: . . . I believe I am an original, first and joint inventor (if plural names are listed below) of **the subject matter which is claimed and for which a patent is sought on the invention** entitled: "PEPTIDES FROM THE hPTH (1-37) SEQUENCE, **the specification of which . . . was filed on September 22, 1995 as PCT International Application No. PCT/EP95/03757** . . . .

(Woodmansee Decl., Ex. D at p.62) (emphasis added).

The '790 patent identifies only three inventors, not four. (Woodmansee Decl., Ex. C at p. 30) The '790 patent identifies Adermann, Hock and Mägerlein as inventors. (*Id.*) Although he was named as an inventor in connection with the PCT Application (and the underlying German patent), Wolf-George Forssmann was never named as an inventor in connection with the application in the United States for the '790 patent.

III. ARGUMENT

A. The Naming Of The Correct Inventors Is A Condition Of Patentability

In *Pannu v. Iolab Corp.*, 155 F.3d 1344 (Fed. Cir. 1998), the Federal Circuit explained the statutory basis requiring a finding of invalidity where a patent fails to name the correct inventors. The Federal Circuit explained that Section 102 establishes the "conditions of patentability" that must be satisfied in order to obtain a valid patent. *Id.* at 1348-49. In particular, Section 102(f) provides that "[a] person shall be entitled to a patent unless -- he did not himself invent the subject matter sought to be patented." 35 U.S.C. § 102(f). "Since the word 'he' [in Section 102(f)] refers to the specific inventive entity named on the patent . . . this subsection **mandates that a patent accurately list the correct inventors of a claimed invention** . . ." *Pannu* at 1349 (emphasis added). "Accordingly, if nonjoinder of an actual inventor is proved by clear and convincing evidence, . . . **a patent is rendered invalid**. *Id.* (citations omitted) (emphasis added).

Although the failure to name the correct inventors renders a patent invalid, the Patent Act provides a procedure for correcting inventorship errors that have been established in ongoing litigation. In *Pannu*, the Federal Circuit held that the operation of section 102(f) in the context of ongoing litigation is "ameliorated" by the ability to correct inventorship errors through a judicial hearing pursuant to section 256 of the Patent Act. *Id* at 1350. "Upon such a finding of incorrect inventorship, a patentee may invoke section 256 to save the patent from invalidity." *Id.* Specifically, the Federal Circuit acknowledged: "Non-joinder may be corrected 'on notice and hearing of all the parties concerned' and upon a showing that the error occurred without any deceptive intent on the part of the unnamed inventor." 35 U.S.C. § 256. "If a patentee demonstrates that inventorship can be corrected as provided for in section 256, a district court must order correction of the patent, thus saving it from being rendered invalid." *Id.* at 1350.

B. The Undisputed Evidence Establishes That The '790 Patent Suffers From Nonjoinder Of An Inventor: Wolf-Georg Forssmann

When one compares the PCT Application with the initial application in the United States for the '790 patent, it is apparent that Wolf-Georg Forssmann should have been named as an inventor on the '790 patent. The application that issued as the '790 patent was the "national stage" in the United States of PCT Application WO 96/10041. (*See, e.g.*, Woodmansee Decl., Ex. C at p. 30; Ex. D at p. 62) The filing of the PCT Application in 1995 had the same effect as an application normally filed in the United States PTO. "An international application designating the United States shall have the effect, from its international filing date under article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office except as otherwise provided in section 102(e) of this title." 35 U.S.C. § 363; *see also Chisum* § 14.02 [4] (noting that, to commence the "national phase" in the U.S. based on a prior PCT Application, the applicant must pay a filing fee, file a copy of the international application and an English translation).

"The general purpose of the PCT is to provide a single set of standards and procedures for the filing of patent applications on the same invention in any of the over ninety PCT member countries." *Chisum* § 14.02 [4]n.1 (quoting Department of Commerce, Patent and Trademark Office, Revision of Patent Cooperation Treaty Application Procedure, 63 Fed. Reg. 66040, 66041 (Dec. 1, 1998)) (emphasis added). Because the PCT process is intended to permit multi-jurisdictional patenting of the same invention, the inventorship of the national stage application should follow the inventorship designation in the originating country. *Chou v Univ.of Chicago*, 254 F.3d 1347, 1360 (Fed. Cir. 2001) (noting that inventorship on PCT and foreign national stage applications "normally follows the inventorship designation in the originating country").

Although '790 was the same application and the same invention as the PCT and the underlying German patent, Forrsmann was not named as an inventor on the '790 patent. (Woodmansee Decl., Ex. C at p. 30; Ex. D at pp. 62-63) Only Adermann, Hock and

Mägerlein were named as inventors on the U.S. application. (Woodmansee Decl., Ex. D at pp. 62-63) Only Adermann, Hock and Mägerlein signed declarations with inventor's oaths in connection with the U.S. application. (*Id.*) Although Forssmann was listed as an inventor on the PCT Application (and on the underlying German patent), he was not named in connection with the U.S. application and he did not sign a declaration and inventorship oath. Given the legal relationship between the PCT Application and the application for the '790 patent -- the same application for the same invention -- Forssmann should have been an inventor of the subject matter disclosed and claimed in the '790 patent. *See, e.g., Chou* at 1360.[1]

It is clear that Forssmann should have been named as an inventor on the application that issued as the '790 patent. He was not. The application for the '790 patent therefore failed to meet one of the most basic requirements for patentability -- naming all the correct inventors. The '790 patent is invalid and unenforceable unless Nichols seeks to correct the omission in this Court pursuant to section 256. *Pannu* at 1349.

C. Nichols Must Either Immediately Move To Correct The Inventorship Error In Court Or Have The Patent Declared Invalid

Because correct inventorship is a condition of patentability, a patentee cannot enforce a patent until it has taken the corrective steps required by statute. *Id.* at 1349 (holding that patentee "must claim entitlement to relief under the statute" or have its patent declared invalid); *see also Merry Mfg. Co. v. Burns Tool Co.*, 335 F. 2d 239, 242 (5th Cir. 1964) ("The patent is unenforceable until corrective steps are taken" and if correction cannot be made "the

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[1] Nichols may attempt some explanation for its failure to follow the normal rule that inventorship of national stage applications follows the inventorship designation in the originating country. Scantibodies submits that there is no reasonable explanation for applicants' failure to name Forssmann as an inventor of the '790 patent in light of the identical subject matter

(Footnote continues on following page.)

unenforceability ripens into invalidity"); *Mas-Hamilton Group v. LaGard, Inc.*, 21 F. Supp.2d 700, 711 (E.D.Ky. 1997) ("Such a patent with inventorship defects is unenforceable until corrective steps are taken.").

Although section 256 provides an opportunity to correct inventorship errors, Nichols cannot avoid summary judgment by asserting that the patent *might* still be corrected at the PTO. In *Pannu*, the Federal Circuit held that the mere possibility of correction under section 256 does not allow a patentee to escape invalidation of a patent due to misjoinder. In order to avoid a finding of invalidity by this Court, Nichols must immediately commence an action for judicial correction upon notice and hearing of all concerned parties.

> [A] patent with improper inventorship does not avoid invalidation simply because it might be corrected under section 256. Rather, the patentee *must claim entitlement to relief under the statute and the court must give the patentee an opportunity to correct the inventorship*. If the inventorship is successfully corrected, section 102(f) will not render the patent invalid. On the other hand, if the patentee does not claim relief under the statute and a party asserting invalidity proves incorrect inventorship, the court should hold the patent invalid for failure to comply with section 102(f).

Pannu at 1350-51 (emphasis added). The Federal Circuit held in the context of ongoing litigation "[n]onjoinder may be corrected 'on notice and hearing of all parties concerned.'" *Id.* at 1350. Now that incorrect inventorship has been raised in this action, that hearing can only take place in this Court.

In short, Nichols is before this Court with a clearly invalid and/or unenforceable patent. Nichols should not be allowed to proceed with an action for infringement of the '790 patent under that circumstance. Nichols has two choices: either it must immediately commence an action for

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(Footnote continued from previous page)

described in the related applications, and looks forward to addressing whatever excuses Nichols may proffer.

judicial correction of inventorship under section 256, or else face this Court's ruling that the '790 patent is invalid for incorrect inventorship. *See id.*

A similar situation was addressed by the Massachusetts district court in *PerSeptive Biosystems v. Pharmacia Biotech*, 12 F. Supp.2d 69 (D.Mass. 1998). In *PerSeptive Biosystems*, the district court granted defendant's cross-motion for summary judgment that plaintiff's patents were invalid for nonjoinder of the true inventors. *Id.* at 75. The court ordered the plaintiff to move to correct inventorship pursuant to section 256 within ten days of the summary judgment order, or the action would be dismissed. *Id.* at 87. Plaintiff subsequently moved for judicial correction in the district court.

Scantibodies respectfully requests that this Court follow a similar procedure in this case. In light of the undisputed evidence and the Federal Circuit's ruling in *Pannu*, Scantibodies requests that the Court require Nichols to commence within ten days an action for judicial correction of inventorship pursuant to section 256 on notice and hearing of all interested parties. If Nichols does not promptly do so, Scantibodies requests that the Court enter summary judgment of the invalidity of the '790 patent under section 102(f). *Pannu* at 1350-51.

D. If Nichols Seeks Judicial Correction Of Inventorship, The Infringement Action Should Be Stayed Pending Hearing On Inventorship Issues

Assuming Nichols does seek judicial correction pursuant to section 256, Scantibodies requests that the action against it for allegedly infringing the '790 patent be stayed pending full discovery and hearing of the inventorship issues. A costly action for infringement of a patent that is invalid for nonjoinder of inventors is "premature" while the inventorship remains uncorrected. *See Burroughs Wellcome Co. v. Barr Lab.*, 40 F.3d 1223, 1227 (Fed. Cir. 1994) ("If Barr and Novopharm are correct, then [the omitted inventors] should have been named as joint inventors and the resolution of Burroughs Wellcome's infringement suit

is premature."). Scantibodies should not be forced to spend any additional sums on a premature infringement suit that should not even have been filed unless and until the nonjoinder of true inventors had been corrected.

IV. CONCLUSION

This motion presents a simple issue as to which there can be no genuine disputes. The '790 patent is invalid due to nonjoinder of Forssmann. Nichols must now seek judicial correction of inventorship on notice and hearing of all concerned parties or have its patent declared invalid pursuant to section 102(f). In either case, Nichols should not be permitted to force Scantibodies to expend further resources on an infringement action that is, as a matter of law, premature.

Dated: May 16, 2002

DAVID C. DOYLE
ERIC M. ACKER
M. ANDREW WOODMANSEE
SHANNON M. DAILEY
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By: _____
David C. Doyle

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SCANTIBODIES LABORATORY, INC.